OCT 31 1996 K962764

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetoencephalograph
Common/Usual Name:	Magnetoencephalographic (MEG) Device
Proprietary Name:	Neuromag-122
Establishment Registration:	Manufacturer: Neuromag Ltd. P.O. Box 357 00511 Helsinki, Finland Phone: +358-0-394 101 Fax: +358-0-3941 203 FDA Facility Registration: # 9680891 United States Representative: Picker International, Inc. 595 Miner Road Highland Heights, OH 44143 FDA Owner Number: #1580240
Performance Standards	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Neuromag-122 system is intended for use as a magneto encephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

3. Device Description

This device integrates 122 SQUID planar gradiometers with medical super-computers and data acquisition software in order to measure the differences in the magnetic signals generated by the intracellular dendritic currents. These detectors are positioned in a helmet shaped array which

gives the user the ability to record the electrical activity of the entire surface of the brain simultaneously without having to move the position of the probe.

4. Safety and Effectiveness

The Neuromag-122 is substantially equivalent to the Biomagnetic Technologies Magnes Single (K901215A) in safety and effectiveness. The following chart has been compiled to demonstrate Neuromag-122's substantial equivalence to this device.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	Neuromag-122	Biomagnetic Technologies Magnes Single (K901215A)
No. of SQUID detectors / channels for MEG data	122	37
No. of auxiliary channels for other types of data (e.g EEG)	166 (typically use 32 for EEG)	51
Gradiometer	Two orthogonal planar-first-order gradiometers per location	First order axial gradiometer
Intersensor spacing	43-44 mm	20 mm
Gradiometer placement	Sixty-one locations distributed across helmet-shaped lower tip of dewar. Radius of curvature of helmet is 83 mm (front-portion) and 91 mm (back-portion).	Positioned in a circular array (diameter 14.4 cm) over a concave spherical surface with a 12.2 cm radius of curvature.
Cryogen Used	Liquid Helium	Liquid Helium
Coverage	One acquisition to cover entire head	Six to ten acquisitions to cover entire head.
Gantry	Floor mounted, standard gantry tilts up to 30°. Optional gantry tilts to 45°.	Suspended from ceiling, gantry can tilt up to 45°.
Patient Position	Seated or Supine. Optional chair insert for children.	Seated or Lying on back or side.
Head Position Indicator	Available	Available

Computer	Hewlett Packard workstation with UNIX environment.	SUN workstation with the UNIX environment
Networking Capabilities	Ethernet connections to other workstations available	Ethernet connections to other workstations available
Magnetic Shielded Room Accessories	Video monitor and two-way intercom for monitoring patients.	Interior DC lights, video cameras, and two-way intercom for monitoring patients
Intended Use	Based on the product literature: **The Magnes Single** non-invasively detects small biomagnetic signals produced by the brain and provides information about the location of electrically active nerve tissue responsible for producing these signals. The data is presented to the physicians in an MEG image, from which they may draw information about the location of critical brain functions relative to brain anatomy. The **Neuromag-122 system** is intended for use as a magneto encephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.	